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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : KUKOLJ, G. et al) Art Unit: To be assigned
U.S. Appln. No. : To be assigned) Examiner: To be assigned
Confirmation No. : To be assigned
U.S. Filing Date : October 16, 2003
Title of Invention : Self-replicating RNA Molecule from Hepatitis C Virus
Attny. Docket No.: 13/083-2-C1

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

October 16, 2003

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described herein below. A copy of each of the non-patent documents can be found in the parent case, U.S. Patent Application Serial No. 10/029,907, filed December 21, 2001. A copy of each of the two U.S. Patent application publications is not submitted pursuant to waiver of 37 CFR § 1.98 (a)(2).

1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

- A statement as specified in 37 C.F.R. §1.97(e) [see below]; or
- The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

1.97(e).

Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

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1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,



Susan K. Pocchiari
Attorney for Applicant(s)
Reg. No. 45,016

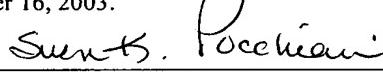
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(Use as many sheets as necessary)

Sheet

1

5

Completer if Known

Application Number	To be assigned
Filing Date	October 16, 2003
First Named Inventor	G. KUKOLJ, et al
Art Unit	To be assigned
Examiner Name	To be assigned

Attorney Docket Number 13/083-2-C1

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 98/04008	01-29-1998	Motorola Inc.		
		WO 98/39031	9-11-1998	Washington University		
		WO 00/66623	11-9-2000	Boehringer Ingelheim		
		WO 01/89364	11-29-2001	Washington University		

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				<i>Filing Date</i>	October 16, 2003
				<i>First Named Inventor</i>	G. KUKOLJ, et al
				<i>Art Unit</i>	To be assigned
				<i>Examiner Name</i>	To be assigned
Sheet	2	of	5	Attorney Docket Number	13/083-2-C1

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
		FOURNIER, SUREAU et al.; In vitro infection of adult normal human hepatocytes in primary culture by hepatitis C virus; J. Virol.; 1998, V. 79; 2367-2374		
		GRAKOUI, WYCHOWSKI et al.; Expression and Identification of Hepatitis C Virus Polyprotein Cleavage Products; J. Virol.; 1993, V. 67, No. 3; 1385-1395		
		HIIKATA, MIZUSHIMA et al.; Two Distinct Proteinase Activities Required for the Processing of a Putative Nonstructural Precursor Protein of Hepatitis C Virus; J. Virol.; 1993, V. 67, No. 8; 4665-4675		
		BARTENSCHLAGER, AHLBORN-LAAKE et al.; Nonstructural Protein 3 of the Hepatitis C Virus Encodes a Serine-Type Proteinase Required for Cleavage at the NS3/4 and NS4/5 Junctions; J. Virol.; 1993, V. 67, No. 7; 3835-3844		
		REED, XU et al.; Phosphorylation of the Hepatitis C Virus NS5A Protein In Vitro and In Vivo: Properties of the NS5A-Associated Kinase; J. Virol.; 1997, V. 71, No. 10; 7187-7197		
		KHROMYKH, WESTAWAY; Subgenomic Replicons of the Flavivirus Kunjin: Construction and Applications; J. Virol.; 1997, V. 71, No. 2; 1497-1505		
		BEHRENS, GRASSMANN et al.; Characterization of an Autonomous Subgenomic Pestivirus RNA Replicon; J. Virol.; 1998, V. 72, No. 3; 2364-2372		
		MIZUTANI, KATO et al.; Characterization of Hepatitis C Virus Replication in Cloned Cells Obtained from a Human T-Cell Leukemia Virus Type 1-Infected Cell Line, MT-2; J. Virol.; 1996, V. 70, No. 10; 7219-7223		
		MOSER, TRATSCHIN et al.; A Recombinant Classical Swine Fever Virus Stably Expresses a Marker Gene; J. Virol.; 1998, V. 72, No. 6; 5318-5322		
		KEDA, SUGIYAMA et al.; Human hepatocyte clonal cell lines that support persistent replication of hepatitis C virus; Virus Research; 1998, V. 56; 157-167		

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		DASH, HALIM et al.; Transfection of HepG2 Cells with Infectious Hepatitis C Virus Genome; Amer. J. Pathology; 1997, V. 151; 363-373		
		KWONG,KIM et al.; Hepatitis C Virus NS3/4A protease; Antiviral Research 1998, V. 40; 1-18		
		LANFORD, SUREAU et al; Demonstration of in Vitro Infection of Chimpanzee Hepatocytes with hepatitis C Virus Using Strand-Specific RT/PCR; Virology; 1994, V. 202; 606-614		
		LESBURG, CABLE et al; Crystal structure of the RNA-dependent RNA polymerase from hepatitis C virus reveals a fully encircled active site; Nat. Struc. Biol; 1999 V.6 No. 10; 937-943		
		LOHMANN, KORNER et al; Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line; Science; 1999, V.285; 110-113		
		LOHMANN, KORNER et al; Mutations in Hepatitis C virus RNAs Confering Cell Culture Adaptation; J. Virology; 2001, V. 75, No. 3, 1437-1449		
		LOVE, PARGE et al; The Crystal Structure of Hepatitis C Virus NS3 Proteinase Reveals a Trypsin-like Fold and a Structural Zinc Binding Site; Cell; 1996, V. 87, 331-342		
		SHIMIZU, Purcell et al; Correalation between the infectivity of hepatitis C virus in vivo and its infectivity in vitro; Proc. Natl. Acad Sci. USA; 1993, V. 90; 6037-6041		
		YANAGI, ST. CLAIRE et al; In vivo analysis of the 3' untranslated region of the hepatitis C virus after in vitro mutagenesis of an infectious cDNA clone; Proc. Natl. Acad. Sci. USA 1999, V. 96, 2291-2295		

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Sheet	4	of	5	Attorney Docket Number	13/083-2-C1

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		BRESSANELLI, TOMEI et al.; Crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus; PNAS; 1999, V. 96, No. 23; 13034-13039		T ²
		KIM, MORGESTERN et al.; Hepatitis C virus NS3 RNA helicase domain with a bound oligonucleotide: the crystal structure provides insights into the mode of unwinding; Structure; 1998, V. 6; 89-100.		
		YAN, LI et al.; Complex of NS3 protease and NS4A peptide of BK strain hepatitis C virus; A 2.2 Å resolution structure in a hexagonal crystal form; Protein Science; 1998, V. 7; 837-847		
		YAO, HESSON et al.; Structure of the hepatitis C virus RNA helicase domain; Nature Structural Biology; 1997, V. 4, No. 6; 463-467		
		ITO, MUKAIKAWA et al.; Cultivation of hepatitis C virus in primary hepatocyte culture from patients with chronic hepatitis C results in release of high titre infectious virus; J. Gen. Virol.; 1996, V. 77; 1043-1054		
		YOO, SELBY et al.; Transfection of a Differentiated Human Hepatoma Cell Line (Huh7) with In Vitro-Transcribed Hepatitis C Virus (HCV) RNA and Establishment of a Long-Term Culture Persistently Infected with HCV; J. Virol.; 1992, V. 69, No. 1; 32-38		
		AGO, ADACHI et al.; Crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus; Structure; 1999, V. 7; 1417-1426		
		BLIGHT, KOLYKHALOV et al.; Efficient Initiation of HCV RNA Replication in Cell Culture; Science; 2000, V. 290; 1972-1974		

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Sheet	5	of	5	Attorney Docket Number	13/083-2-C1

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		CHO, HA et al.; Crystal Structure of RNA Helicase from Genotype 1b Hepatitis C Virus; J. Biol. Chemistry; 1998, V. 273, No. 24; 15054-15052		
		GALE JR., KORTH et al.; Evidence that Hepatitis C Virus Resistance to Interferon is Mediated through Repression of the PKR Protein Kinase by the Nonstructural 5A Protein; Virology; 1997, V. 230; 217-227		
		GRAKOUI, MCCOURT et al.; A second hepatitis C virus-encoded proteinase; Proc. Natl. Acad. Sci. USA; 1993, V. 90; 10583-10587		
		GOU, JU-TAO et al.; Effect of Alpha Interferon on the Hepatitis C virus Replicon; J. Virol.; 2001, 75(18):8516-8523		
		HIIKATA, MAKOTO et al.; Gene mapping of the putative structural region of the hepatitis C virus genome by in vitro processing analysis; Proc. Natl. Acad. Sci.; 1991, 88:5547-5551		
		KIM, DONG WOOK et al.; C-Terminal Domain of the Hepatitis C Virus NS3 Protein Contains an RNA Helicase Activity; 1995, 215(1):160-166		
		KIM, J.-E. et al; Subcellular localization of hepatitis C viral proteins in mammalian cells; Arch Virol.; 1999, 144:329-343		
		KIM, J.L. et al; Crystal Structure of the Hepatitis C Virus NS3 Protease Domain Complexed with a Synthetic NS4A Cofactor Peptide; Cell; 1996, 87:343-355		
		KRIEGER, NICOLE, et al; Enhancement of Hepatitis C Virus RNA Replication by Cell Culture-Adaptive Mutations; J. of Virol.; 2001, 75(10):4614-4624		
		International Search Report issued March 3, 2003 for PCT/CAD1/01843 the counterpart of Parent U.S. Application 10/029,907.		

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